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Amendment
Attorney Docket No. S85.2H-7189-US02

REMARKS

This amendment is in response to the Office Action dated July 8, 2003. Claims 1 – 12 are pending in this application. The Office Action rejected claims 1 – 6 and 12. The Examiner withdrew claims 7 – 11 from consideration.

By this Amendment, claims 13 – 17 are added. Reconsideration in view of the following remarks is respectfully requested.

Claim Rejections

The Office Action rejects, under 35 USC § 103, claims 1 – 6 and 12 over Bonutti (U.S. 5,577,517). These rejections are respectfully traversed.

Applicants assert that Bonutti does not disclose or suggest a tool for directing bone replacement material into a fill space, the “distal end including at least one deflector opening for deflecting the bone replacement material out of said tube and into the fill space at an angle relative to a longitudinal axis of said tube” as recited in independent claim 1. Further, Applicants assert that Bonutti teaches away from the claimed invention.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings to produce the claimed invention. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Bonutti discloses a percutaneous **bone removal apparatus 10** having a flexible shaft 14 and a cutting tip 16. The cutting tip 16 has a cutting edge 40 and an opening 38 through which tissue fragments severed by the cutting tip may be removed by suction. The tissue fragments are then carried back through the shaft 14 to eventually become trapped in a strainer 28. See Figures 1 and 3, and column 5, lines 27 – 60.

Bonutti in no way discloses or suggests using the bone removal apparatus 10 for directing bone replacement material *into* a fill space. The Examiner has provided absolutely no

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suggestion that the Bonutti bone removal apparatus would even be suitable for such use.

In fact, Bonutti teaches away from using the bone removal apparatus for directing material into a fill space. Bonutti discloses that tissue fragments removed using the bone removal apparatus and harvested may be used as a graft material 190. The graft material 190 may be inserted into a biodegradable sac 192, and the sac may be inserted into the bone using a cannula 180. Alternatively, loose graft material 190 may be inserted through a funnel 196 and sleeve 198 located within the cannula. See Figures 18 and 19A, and column 9, lines 26 – 66.

Thus, Bonutti teaches methods of inserting graft material other than by using the bone removal apparatus. Therefore, Bonutti teaches away from using the bone removal apparatus to insert material into a defined space.

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)

Therefore, Bonutti does not disclose or suggest the invention as recited in independent claim 1. Applicants respectfully submit that independent claim 1 is not made obvious in light of Bonutti. Claims 3 – 6 and 12 depend from independent claim 1 and therefore also are not made obvious by Bonutti for at least the reasons discussed above. Accordingly, Applicants respectfully request the withdrawal of the rejections under 35 USC § 103.

Added Claims

Applicants submit herewith claims 13 – 17. These claims are identical to claims 1 and 3 – 6 as amended by the Preliminary Amendment dated July 17, 2002.

In the Final Office Action of March 10, 2003, the Examiner maintained the 35 U.S.C. §103(a) obviousness rejection of claims 1 – 6 in light of Bonutti (U.S. 5,577,517) from the previous Office Action of October 1, 2002.

In response to the Final Office Action, Applicants filed a Request for Continued Examination and amended claims 1 and 3 – 6 to include further limitations directed to elements of a system for filling a bone cavity. However, in the currently outstanding Office Action dated July 24, 2003, the Examiner again rejected claims 1 and 3 – 6, as amended, over Bonutti. Applicants maintain the position that the prior versions of claims 1 and 3 – 6, as amended by the

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Preliminary Amendment dated July 17, 2002, are not made obvious in light of Bonutti. Therefore, Applicants submit claims 13 – 17, which are identical to claims 1 and 3 – 6 as amended by the Preliminary Amendment, for consideration along with the following remarks.

Applicants assert that Bonutti does not disclose or suggest a tool for directing bone replacement material into a fill space, the “distal end including at least one deflector opening for deflecting bone replacement material out of said tube at an angle relative to a longitudinal axis of said tube,” as recited in independent claim 13. Further, Applicants assert that Bonutti teaches away from the invention of claim 13, and direct the Examiner’s attention to the previous section wherein the rejections of claims 1 – 6 and 12 are discussed.

In the Final Office Action of March 10, 2003, the Examiner cited *Ex Parte Masham*, 2 USPQ2d 1647 (1987) for the assertion that “a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.”

Applicants assert that the Examiner has misapplied *Ex Parte Masham*, which applies to the concept of anticipation under 35 U.S.C. §102, not obviousness under 35 U.S.C. §103. When a claimed device is structurally identical to a device in the prior art, a claim limitation with respect to the intended use will not save the claim from anticipation because the structurally identical prior art device could inherently be used in the same way.

Thus, in rejecting the claims of the present application under 35 U.S.C. §103, the Examiner has applied the concepts of structural identity and inherency. However, consideration of an inherent quality is relevant only to anticipation, not obviousness. *Jones v. Hardy*, 220 USPQ 1021 (Fed. Cir. 1984).

Further, Applicants have repeatedly asserted that the claimed invention is not structurally identical to the Bonutti bone removal apparatus. Applicants have repeatedly asserted that the Bonutti disclosure does not teach or suggest all of the limitations of the present claims or provide any motivation to modify the bone removal apparatus to arrive at the presently claimed device, both of which would be required for a proper finding of obviousness under 35 U.S.C. §103.

Therefore Applicants respectfully submit that independent claim 13, and claims 14 – 17 depending therefrom, are not made obvious in light of Bonutti.

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Restriction Requirement

The Examiner withdrew claims 7 – 11 from consideration as reading on Figures 9 – 13, and thus being directed to a non-elected species. Applicants assert that claims 7 – 11 should be considered as they read on Figures 1 – 4.

Further, Applicants assert that claims 7 – 11 depend from independent claim 1, which applicants believe to be allowable. As such, Applicants submit that claims 7 – 11 are allowable at least because they depend from an allowable base claim.

Additionally, in the Office Action dated October 1, 2002, the Examiner acknowledged that claim 1 as amended by the Preliminary Amendment dated July 17, 2002 was broad enough to cover all three species recited in the restriction requirement. Claim 13 submitted herewith is identical to claim 1 as amended by the Preliminary Amendment, and is believed to be allowable. Therefore, applicants respectfully request withdrawal of the restriction requirement and allowance of claims 7 – 11.

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CONCLUSION

Based on at least the foregoing remarks, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1 and 3-17 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September, 2003

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